

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

**TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)  
CONCERNING A SUBMISSION UNDER 35 U.S.C. 371**

ATTORNEY'S DOCKET NUMBER

**222.1105**

U.S. APPLICATION NO. (If known see 37 C.F.R. 1.5)

To Be Assigned

**104517858**INTERNATIONAL APPLICATION NO.  
**PCT/GB03/02622**INTERNATIONAL FILING DATE  
**18 June 2003**

PRIORITY DATE CLAIMED

**18 June 2002**

## TITLE OF INVENTION

**GASTRORETENTIVE DRUG DELIVERY SYSTEM COMPRISING AN EXTRUDED HYDRATABLE POLYMER**

## APPLICANT(S) FOR DO/EO/US

**Hassan MOHAMMAD**

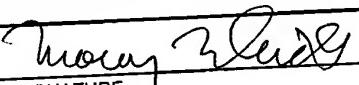
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1.  This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2.  This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3.  This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4.  The US has been elected (Article 31).
5.  A copy of the International Application as filed (35 U.S.C. 371(c)(2))
  - a.  is attached hereto (required only if not communicated by the International Bureau).
  - b.  has been communicated by the International Bureau.
  - c.  is not required, as the application was filed in the United States Receiving Office (RO/US).
6.  An English language translation of the International Application as filed (35 U.S.C. 371(c)(2))
  - a.  is attached hereto.
  - b.  has been previously submitted under 35 U.S.C. 154(d)(4).
7.  Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
  - a.  are attached hereto (required only if not communicated by the International Bureau).
  - b.  have been communicated by the International Bureau.
  - c.  have not been made; however, the time limit for making such amendments has NOT expired.
  - d.  have not been made and will not be made.
8.  An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9.  An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10.  An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

## Items 11 to 20 below concern document(s) or information included:

11.  An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12.  An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13.  A preliminary amendment.
14.  An Application Datasheet under 37 CFR 1.76.
15.  A substitute specification.
16.  A power of attorney and/or change of address letter.
17.  A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825.
18.  A second copy of the published international application under 35 U.S.C. 154(d)(4).
19.  A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20.  Other items or information:
  - Copies of four (4) cited references;
  - Request to Correct Inventor's Name;
  - Return Receipt Postcard

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

U.S. APPLICATION NO. (If known, see 37 C.F.R. 1.50) <b>Not Yet Known</b>	INTERNATIONAL APPLICATION NO. <b>PCT/GB03/02622</b>	ATTORNEY'S DOCKET NO. <b>222.1105</b>	
		CALCULATIONS	PTO USE ONLY
		\$	
		\$	
		\$	
		<b>\$1000.00</b>	
<b>TOTAL OF ABOVE CALCULATIONS = \$1000.00</b>			
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.			
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE
21 - 100	/50		x \$250.00
Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(e)). + \$0.00			
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE
Total Claims	8 - 20 = 0		x \$50.00
Independent Claims	2 - 3 = 0		x \$200.00
MULTIPLE DEPENDENT CLAIM(S) (if applicable) + \$360.00			
<b>TOTAL OF ABOVE CALCULATIONS = \$1000.00</b>			
<input type="checkbox"/> Applicant claims small entity status. See 37 C.F.R. 1.27. The fees indicated above are reduced by ½.			
<b>SUBTOTAL = \$1000.00</b>			
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(f)). + \$0.00			
<b>TOTAL NATIONAL FEE = \$1000.00</b>			
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property + \$40.00			
<b>TOTAL FEES ENCLOSED = \$1040.00</b>			
		Amount to be refunded:	\$
		Amount to be charged:	\$
a. <input checked="" type="checkbox"/> A check in the amount of <u>\$1040.00</u> to cover the above fees is enclosed.			
b. <input type="checkbox"/> Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees. A duplicate copy of this sheet is enclosed.			
c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>50-0552</u> . A duplicate copy of this sheet is enclosed.			
d. <input type="checkbox"/> Fees are to be charged to a credit card. <b>WARNING:</b> Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.			
NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.			
SEND ALL CORRESPONDENCE TO: <b>Davidson, Davidson &amp; Kappel, LLC 485 Seventh Avenue, 14th Floor New York, NY 10018 (212)-736-1940</b>			
 SIGNATURE <b>Morey B. Wildes</b>			
NAME <b>36,968</b>			
REGISTRATION NUMBER			

10/517858

DT12 Rec'd PCT/PTO 14 DEC 2004

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

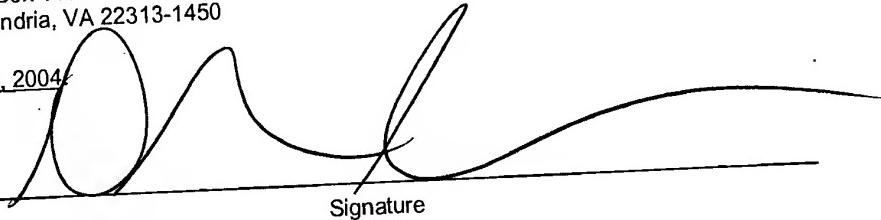
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

## Certificate of Express Mailing under 37 CFR 1.10

I hereby certify that this correspondence is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10 in an envelope addressed to:

Mail Stop: PCT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

on December 14, 2004  
Date



Shane Underdue

Typed or printed name of person signing Certificate

(212) 736-1940

Registration Number, if applicable

Telephone Number

EV 383927663 US

("Express Mail" Mailing Label Number)

Note: Each paper must have its own certificate of mailing by Express Mail, or this certificate must identify each submitted paper.

Re.: Docket No.: 222.1105

Applicant(s): Hassan MOHAMMAD

Serial No.: National Phase of International Patent No. PCT/GB03/02622

Invention: GASTRORETENTIVE DRUG DELIVERY SYSTEM COMPRISING AN EXTRUDED HYDRATABLE POLYMER

Filing Date: June 18, 2003

- Transmittal Letter to the US DO/EO re filing under 35 U.S.C. 371 (2 pages);
- Copy of Published International Application No. PCT/GB/02622 (WO 03/105812 A1) with International Search Report (26 pages);
- Declaration and Power of Attorney (1 page);
- Information Disclosure Statement (1 page) with Form PTO-1449 (1 page) with copies of 4 cited references;
- Recordation Form (1 page) with Assignment (2 pages);
- Preliminary Amendment (4 pages);
- Application Data Sheet (2 pages);
- Request to Correct Inventor's Name (2 pages);
- Checks in the total amount of \$1040.00 and
- Certificate of Express Mailing

This collection of information is required by 37 CFR 1.10. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.8 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.